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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,675	05/23/2001	Mark Marchionni	04585/049002	3830
21559	7590	03/03/2004	EXAMINER	
CLARK & ELBING LLP			NICHOLS, CHRISTOPHER J	
101 FEDERAL STREET			ART UNIT	
BOSTON, MA 02110			PAPER NUMBER	

1647

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/864,675	Applicant(s) MARCHIONNI, MARK	
	Examiner Christopher Nichols, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 1-54, 58 and 60-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55-57 and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 12 (claims 55-57 and 59) drawn to pure NRG-2 nucleic acid molecules in the Response filed 9 October 2003 is acknowledged. Claims **1-54, 58, and 60-69** are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Drawings

2. The drawings are objected to because the labels in Figure 5 are not legible; Examiner respectfully suggests typing or word-processing said labels on a replacement figure. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "1-15" in Figure 10. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "11A, 11B" should be included in Figure 11, likewise "14A, 14B" should be included in Figure 14. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims **55, 56, 57, and 59** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The term "substantially" in claims 55, 56, 57 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Neither the Specification nor the art satisfactory and clearly defines "substantially" for the phrases in which it is used "substantially pure" and "substantially identical". For instance the American Heritage Dictionary defines "substantially" as: "Of, relating to, or having substance; material; True or real; not imaginary; Solidly built; strong; Ample; sustaining: *a substantial breakfast*; Considerable in importance, value, degree, amount, or extent: *won by a substantial margin*; Possessing wealth or property; well-to-do." Thus no unambiguous definition may be attributed to "substantially" as it is a relative term. The Examiner respectfully suggests the standard language of "isolated" in lieu of "substantially pure" as exemplified at the end of the Office Action.

Summary

7. No claims are allowed.

Art Unit: 1647

8. The following patents and published patent applications were found by the Examiner during the art search while not prior art are considered pertinent to the instant application:

a. US 2004/0018181 (11 September 2000) Kufe & Ohno

(discloses sequences with 100% sequence homology to SEQ ID NO: 2 and 95.6% sequence homology to SEQ ID NO: 4)

b. WO 02/22685 A2 (21 March 2002) Kufe & Ohno

(discloses sequences with 100% sequence homology to SEQ ID NO: 2 and 95.6% sequence homology to SEQ ID NO: 4)

9. The following claims drafted by the Examiner and considered to distinguish patentably over the art of record in this application, are presented to applicant for consideration including rejoinder of some withdrawn claims.

Claims 1-54 (Cancelled)

Claim 55 (Original) An isolated ~~substantially pure~~ nucleic acid molecule comprising a sequence encoding a polypeptide comprising the amino acid sequence set forth in SEQ ID Nos: 2 or 4.

Claim 56 (Original) An isolated ~~substantially pure~~ nucleic acid molecule ~~comprising a nucleic acid sequence that is substantially identical to the nucleic acid sequence~~ comprising the nucleic acid sequence set forth in SEQ ID Nos: 1 or 3.

Art Unit: 1647

Claim 57 (Original) An isolated ~~substantially pure~~ nucleic acid molecule consisting of the nucleic acid sequence set forth in SEQ ID Nos: 1 or 3.

Claim 58 (Cancelled)

Claim 59 (Original) A vector comprising the nucleic acid molecule of claim 55, operably linked to a promoter.

Claim 60 (Currently Amended) The vector of claim 59, wherein said vector is ~~a gene therapy~~ an expression vector.

Claim 61 (Currently Amended) A transformed host cell comprising the vector of claim 60.

Claim 70 (New) A vector comprising the nucleic acid molecule of claim 57, operably linked to a promoter.

Claim 71 (New) The vector of claim 70, wherein said vector is expression vector.

Claim 72 (Currently Amended) A transformed host cell comprising the vector of claim 71.

Claim 73 (New) A method of producing a polypeptide comprising SEQ ID NO: 2, said method comprising:

Art Unit: 1647

culturing host cell comprising SEQ ID NO: 1 under conditions to express the polypeptide comprising SEQ ID NO: 2, and
purifying said polypeptide from the cell culture.

Claim 74 (New) A method of producing a polypeptide comprising SEQ ID NO: 4, said method comprising:

culturing host cell comprising SEQ ID NO: 3 under conditions to express the polypeptide comprising SEQ ID NO: 4, and
purifying said polypeptide from the cell culture.

Claim 75 (New) An isolated polypeptide comprising SEQ ID NO: 2

Claim 76 (New) An isolated polypeptide comprising SEQ ID NO: 4.

Claim 77 (New) An isolated polypeptide consisting of SEQ ID NO: 2

Claim 78 (New) An isolated polypeptide consisting of SEQ ID NO: 4.

10. The Examiner notes that if Applicant wishes to accept these claims, they should be included in the response to this Office Action.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
March 1, 2004


GARY KUNZ
SUPERVISORY PATENT EXAMINER
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